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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,474	12/05/2005	Thomas Hunig	7003/31	6842

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EXAMINER	
OUSPENSKI, ILIA I	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,474	HUNIG, THOMAS	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/5/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed on 09/10/2007, are acknowledged.

Claims 1 – 13 are pending.

2. Applicant's election without traverse of Group I (claims 1 – 9, drawn to a microparticle with a support structure, and CD28-specific superagonistic monoclonal antibodies bonded to the support structure, or a compound mimicking the above) in the reply filed on 09/10/2007 is acknowledged. .

Claims 10 – 13 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 1 – 9 are presently under consideration.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

4. Receipt is acknowledged of foreign priority papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

5. The drawings are objected to because of handwritten notation in Figures 1 – 3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 – 9 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 – 9 are indefinite in the recitation of "a compound mimicking the above" in claim 1, because it is unclear whether the phrase "the above" refers to the microparticle, the support structure, or the antibody. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

For examination purposes, it is assumed that "the above" refers to the antibody.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

8. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 – 9 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a microparticle with CD28-specific superagonistic monoclonal antibodies bonded to it, does not reasonably provide enablement for a microparticle with "a compound mimicking" CD28-specific superagonistic monoclonal antibodies bonded to it. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to make and use the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification does not provide a sufficient enabling description of the generically recited mimicking compounds. The specification does not appear to disclose structural characteristics, or working examples of such compounds, while it was well known in the art at the time the invention was made that molecules having highly diverse structural and biochemical properties can function as "mimicking compounds." For example, Huang (Pharmacology and Therapeutics, 2000, 86: 201 – 215; see entire document) reviews e.g. on page 202 the daunting task faced by the skilled artisan in developing small molecule regulators of protein function, and notes that the process requires long periods of trial and error testing. The structure of such molecules cannot be readily determined by one of skill in the art based upon the guidance provided in the specification as-filed. Therefore, Applicant does not provide a sufficiently enabling disclosure regarding how to make and use compounds mimicking superagonistic anti-CD28 antibodies, other than the disclosed antibodies themselves.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. See In re Fisher, 166 USPQ 18 24 (CCPA 1970). Without sufficient guidance, the structural features of "agonists" are unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

10. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 – 6 are rejected under **35 U.S.C. 102(b)** as being anticipated by Hunig (WO 98/54225; see entire document), as evidenced by Hunig (US Patent No. 6,987,171; see entire document).

It is noted that US Patent No. 6,987,171 is a continuation of the international application PCT/DE98/01499, and the WO 98/54225 document is the publication of the same international application PCT/DE98/0149; thus US Patent No. 6,987,171 and publication WO 98/54225 contain the same disclosure. Therefore, the US Patent is relied upon as providing the disclosure of the WO document.

Hunig teaches monoclonal antibodies to human CD28 which "activate T-lymphocytes without occupancy of an antigen receptor" (column 1, lines 10 – 17 of 6,987,171), also referred to as "direct" antibodies (e.g. columns 1 – 2, bridging paragraph), i.e. superagonistic antibodies. Hunig further teaches that such superagonistic antibodies, when introduced into in vitro culture of lymphoid cells, bind to Fc receptors of non-T cells (e.g. Example 3). Such cells expressing Fc receptors are "microparticles with a support structure" to which the CD28-specific superagonistic monoclonal antibodies are bonded.

Therefore, the reference teachings anticipate the instant claimed invention.

Claims 5 and 6 are included in the rejection, because the exemplary language "preferably" and "for instance" does not limit the scope of the claims to the recited limitations.

12. The following is a quotation of **35 U.S.C. 103(a)** which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 5, and 7 – 9 are rejected under **35 U.S.C. 103(a)** as being obvious over Hunig (WO 98/54225; see entire document), as evidenced by Hunig (US Patent No. 6,987,171; see entire document).

The documents by Hunig have been discussed supra, and teach superagonistic anti-CD28 antibodies bound to cells (microparticles) via Fc receptors (support structure).

Hunig does not specifically exemplify the organic polymer of the support structure activated by treatment with an activation reagent, or the diameter or surface of the support structure.

However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to attach the antibodies to microparticles of the recited dimensions, and activate them by the recited reagents, because such methods were

widely known and practiced in the art. Furthermore, one of skill in the art would be motivated to do so, because of the teachings of Hunig that superagonistic antibodies to CD28 can be used for making pharmaceutical compositions for treatment of diseases (see entire document, in particular, e.g. claims 12 and 15, and paragraphs 0026 and 0035 – 0038).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Conclusion: no claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.
Patent Examiner
Art Unit 1644

November 15, 2007